3-14-05

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV438989355US, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: March 10, 2005 Signature: \_\_

ame Brown

1615

Docket No.: 47961 (70126)

(PÀTENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Eric Begleiter

Application No.: 10/031,765

Confirmation No.: 8373

Filed: January 23, 2002

Art Unit: 1615

For: EDIBLE HOLOGRAPHIC PRODUCTS,

PARTICULARLY PHARMACEUTICALS (as

amended)

Examiner: S. T. Tran

## **RESPONSE TO OFFICE ACTION**

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This is response to the Office Action mailed on February 14, 2005.

Applicant gratefully acknowledges that the Examiner has withdrawn the finality of the Office Action mailed on November 18, 2004.

Applicant notes that the restriction requirement is deemed proper and made final. Claims 1-28 are being examined, and claims 29-72 are withdrawn from consideration.

Applicant also gratefully acknowledges that the IDS submitted on June 18, 2004 is being considered.

Applicant respectfully traverses the rejection of claims 1-28 under 35 USC 102(b) as anticipated by Reif U.S. Patent No. 4,031,200.

ģ

À,

Docket No.: 47961(70126)

First, as noted in Applicant's Response to the November 18, 2004 Office Action filed on January 25, 2005, the Reif '200 patent is the parent application to a divisional case, U.S. Patent No. 4,069,086 to Reif. The relation of these documents is clearly stated on the first page of the '086 patent. By definition, the subject matter of the divisional case is the same as that of the parent case.

Reif '086 was cited by applicant in the initial IDS filed on January 23, 2002.

The Reif '086 patent was considered by the predecessor Examiner,

Dr. Liliana DiNola-Baron. Her first Action on the merits in this case did not cite the Reif '086 patent against any claim.

Dr. DiNola-Baron also considered the Reif '086 reference with connection with the corresponding PCT application, Serial No. US00/21149 filed August 3, 2000, published as WO 01/10464 on February 15, 2001. Initially in the International Search Report of 15 September 2000, Dr. DiNola-Baron found Reif '086 to be in category Y with respect to claims 1-62. However, in her Final Report, claims 1-62 were found to be patentable over Reif '086 and the other art of record. A copy of the Final Report was filed with Applicant's Response on January 25, 2005. No amendments were made in claims 1-28 in the U.S. or PCT cases other than correction of minor typographical errors.

There is no reason that the submission of the parent Reif patent should somehow cause the earlier determinations as to its lack of relevance to the pending claims to change. No new subject matter is present in the Reif '200 patent. The pending claims are as patentable over the Reif '200 patent as they were over the Reif '086 patent.

Docket No.: 47961(70126)

Reif teaches depositing doses of an active ingredient on a web, sealing it between the web and a cover layer, and cutting the sealed web into single dosage units. This is not the present invention, nor does it suggest the present invention. Reif also discloses features such as: an electrostatic technique for adding precise amounts of medication to a film, or to multiple strips of film; preventing the strips of medication

from interacting; fan-folding the strips so the medicated film is not exposed; and making solid, sealed, "unitized" dosage forms from those strips with the chemistry to allow the fan-folded film to be exposed and unwound after digestion. None of these features are pertinent to the present claimed invention.

The present claimed invention relates to a dosage form of any of a wide range of types that creates a holographic image or effect. The Reif '200 patent has nothing to do with holography or putting an image on a standard dosage form. Neither Reif '086 or '200 has a teaching or suggestion of a pharmaceutical dosage form that has "a layer of material bearing a microrelief that conveys information" as required by the pending claims 1-6, or a core with a solid outer layer and a microrelief in said layer as required by claims 7-28. Nor does either Reif patent have a teaching or suggestion that the material is "thermoformable" to receive this microrelief, or "stable" (claims 1-6) to maintain the microrelief suitable for a pharmaceutical dosage form.

Nor does the Reif disclosure relate in any way to dosage forms such as capsules or tablets. The fact that a dosage form can be made using a film or films is not the claimed invention. Claim 1 specifies a layer that carries a microrelief and is thermoformable and stable. Claim 18, as another example, is 1) dependent from claim 1 and 2) specifies that the layer can also assume the role of the core in containing the pharmaceutically active substance.

Application No.: 10/031,765 4 Docket No.: 47961(70126)

Neither Reif patent teaches or suggests any of the novel features of the dependent claim in combination with the features of independent claims 1 and 7. The present invention, unlike the Reif '200 product, can be used for quality control, anti-counterfeiting, and brand identification.

For example, there is no teaching or suggestion in Reif '200 or '086 that the constituent material of the layer carrying a microrelief can display information that indicates the history and efficacy of the dosage form by changing its appearance. See, e.g., claims 3 and 19 and the claims dependent from them

In view of the foregoing comments, applicant urges that the pending claims 1-28 patentably clearly distinguish over the art of record, and are otherwise in condition for allowance.

Dated: March 10, 2005

3

Respectfully submitted,

Peter J. Manus

Registration No.: 26,766 EDWARDS & ANGELL, LLP

P.O. Box 55874

Boston, Massachusetts 02205

(617) 439-4444

Attorney for Applicant